

Message Text

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PAGE 01 STATE 005213

ORIGIN HEW-06

INFO OCT-01 AF-08 ARA-10 EUR-12 EA-09 NEA-10 ISO-00 OES-06
SIG-02 COME-00 IO-13 EB-07 /084 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK

APPROVED BY OES/APT/BMP: WJWALSH, III

DHEW/OIH: BROYSTER

ARA/EX:CJACOBINI(INFO)

NEA/EX:EGABINGTON(INFO)

EA/EX:JRCUNNINGHAM(INFO)

EUR/EX:JLTULL(INFO)

AF/EX:JTIERNEY(INFO)

-----110427Z 130896 /62

P 102242Z JAN 77

FM SECSTATE WASHDC

TO AMEMBASSY MEXICO PRIORITY

AMEMBASSY LA PAZ PRIORITY

AMEMBASSY SANTIAGO PRIORITY

AMEMBASSY BOGOTA PRIORITY

AMEMBASSY SAN JOSE PRIORITY

AMEMBASSY SANTO DOMINGO PRIORITY

AMEMBASSY QUITO PRIORITY

AMEMBASSY GUATEMALA PRIORITY

AMEMBASSY PORT AU PRINCE PRIORITY

AMEMBASSY KINGSTON PRIORITY

AMEMBASSY MANAGUA PRIORITY

AMEMBASSY PANAMA PRIORITY

AMEMBASSY LIMA PRIORITY

AMEMBASSY SAN SALVADOR PRIORITY

AMEMBASSY CARACAS PRIORITY

AMEMBASSY BUENOS AIRES PRIORITY

AMCONSUL SAO PAULO PRIORITY

AMEMBASSY VIENNA PRIORITY

AMEMBASSY BRUSSELS PRIORITY

AMEMBASSY COPENHAGEN PRIORITY

AMEMBASSY HELSINKI PRIORITY

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AMEMBASSY BONN PRIORITY

AMEMBASSY ROME PRIORITY

AMEMBASSY THE HAGUE PRIORITY

AMEMBASSY LISBON PRIORITY

AMEMBASSY MADRID PRIORITY

AMEMBASSY STOCKHOLM PRIORITY

AMEMBASSY BERN PRIORITY

AMEMBASSY LONDON PRIORITY
AMEMBASSY CANBERRA PRIORITY
AMCONSUL HONG KONG PRIORITY
AMEMBASSY JAKARTA PRIORITY
AMEMBASSY TEHRAN PRIORITY
AMEMBASSY TEL AVIV PRIORITY
AMEMBASSY TOKYO PRIORITY
AMEMBASSY SEOUL PRIORITY
AMEMBASSY BEIRUT PRIORITY
AMEMBASSY KUALA LUMPUR PRIORITY
AMEMBASSY WELLINGTON PRIORITY
AMEMBASSY PRETORIA PRIORITY
AMEMBASSY CAIRO PRIORITY
AMEMBASSY TAIPEI PRIORITY
AMEMBASSY TUNIS PRIORITY
AMEMBASSY RABAT PRIORITY

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E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, XX

SUBJECT: DENTAL OPERATING LIGHT, MECHANICAL HAZARD,
(RECALL NO. T-024-7).

1. FDA ADVISES OF THE FOLLOWING PRODUCT RECALL:

PRODUCT INVOLVED: RITTER STARLITE DENTAL OPERATING LIGHT -
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MODEL J. THIS LIGHT IS USED IN DENTIST'S OFFICES TO
SUPPLY LIGHT FOR THE EXAMINATIONS AND ORAL SURGORY.

PRODUCT IDENTIFICATION: PRODUCT IS A LIGHT CONSISTING
OF A GLASS LIKE REFLECTOR, APPROXIMATELY 10 BY 12 INCHES.
THE BULB INSERTS IN THE CENTER OF THE REFLECTOR IN A
PLASTIC UNIT. ON THE END OF THE PLASTIC UNIT ARE THE
LETTERS "RITTER". THE BULB IS APPROXIMATELY 1 1/2 INCHES
LONG AND ABOUT 3/8 INCHES IN DIAMETER. THE LIGHT IS ON
A JOINTED ARM DESIGNED TO BE MOUNTED ON THE WALL, CEILING,
CHAIR OR DENTIST'S WORKING UNIT. THIS LIGHT HAS ALSO
BEEN SOLD ON A CEILING MOUNTED TRACKING SYSTEM.

MANUFACTURER/RECALLING FIRM:

RITTER COMPANY, DIVISION SYBRON CORPORATION, 400 WEST
AVENUE, ROCHESTER, N.Y. 14603. THE MANUFACTURERS OF

THE BULBS USED ARE: (1) SYLVANIA, WINCHESTER, KENTUCKY

AND (2) NORTH AMERICAN PHILLIPS, HIGHTSTOWN, NEW JERSEY.
IT IS NOT KNOWN WHICH BULBS WERE INVOLVED IN COMPLAINTS
TO THE RITTER COMPANY.

2. REASON FOR RECALL: DURING 1975 AND THE FIRST HALF
OF 1976 THE FIRM RECEIVED 10 COMPLAINTS THAT THE BULB
IN THE LIGHT EXPLODED DURING USE. THE COMPLAINTS INCLUDED
BOTH DENTISTS AND PATIENTS BEING BURNED WITH SMALL PIECES
OF HOT GLASS FROM THE BROKEN BULB. IN LATE 1975 AND
EARLY 1976 THE FIRM ATTEMPTED TO INSTALL A PLASTIC COVER
OVER THE REFLECTOR OF EVERY LIGHT IN USE. THE FIRM
SUPPLIED A NUMBER OF PLASTIC COVERS EQUAL TO THE TOTAL
SALES OF EACH OF ITS DEALERS PLUS A 10 PERCENT EXTRA.
THE FIRM INSTRUCTED THE DEALERS TO INSTALL ONE OF THE
COVERS ON EACH OF THEIR CUSTOMERS LIGHTS. FROM 1968-1975
THE FIRM HAS SOLD APPROXIMATELY 30,000 LIGHTS. THE FIRM
ESTIMATES MOST OF THESE ARE STILL IN USE. THE PRODUCT
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SOLD IN 1976 IS REDESIGNED AND IS SHIPPED WITH PLASTIC
COVER INSTALLED. THE FIRM SINCE THE BEGINNING OF 1976
HAS BEEN INCLUDING A NOTICE WITH EACH REPLACEMENT BULB
THAT THE BULB SHOULD NOT BE USED UNLESS THE PLASTIC
REFLECTOR COVER HAS BEEN INSTALLED ON THE LIGHT.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES
TO DETERMINE IF THEY HAVE RECEIVED NOTIFICATION FROM
FIRM CONCERNING THE NECESSITY OF INSTALLATION OF PLASTIC
COVERS TO PREVENT INJURY IN CASE BULB EXPLOSION. ANY
QUESTIONS CONSIGNEES MAY HAVE REGARDING THIS RECALL
SHOULD BE DIRECTED TO THE FIRM.

4. FOREIGN CONSIGNEES AS FOLLOWS:

RITTER DEMEXICO, MEXICO CITY, MEXICO
GENERAL DENTAL, LA PAZ, BOLIVIA
H.A. WIRTH, SANTIAGO, CHILE
DENTAL MEDICO LTDA., BARANQUILLA, COLOMBIA
O. FISCH R.Y.C.A. LTD., SAN JOSE, COSTA RICA
INSULAR TRADING CO., SANTO DOMINGO, DOMINICAN REP.
EQUADER, GUAYQUIL, ECUADOR
DEP.DENT.SAN ANTONIO, GUATEMALA CITY, GUATEMALA
ALMAPHARMA, PORT-AU-PRINCE, HAITI
EWAN D. MACDOUGALL DENTAL, KINGSTON, JAMAICA
ROBERTO TERAN CO., MANAGUA, NICARAGUA

DEP.MED.DENT., SA, PANAMA CITY, PANAMA
MEDI DENTAL, LIMA, PERU
DIST. DENTAL SALVADORENA, SAN SALVADOR, EL SALVADOR

C.A. EQUIPO DENTAL, CARACAS, VENEZUELA
S.A. O'NEILL, BUENOS AIRES, ARGENTINA
DENT'ART SA, SAO PAULO, BRAZIL
RINNERTHALER, LINZ, AUSTRIA
LES DEPOTS DENT. REUNIS, BRUXELLES, BELGIUM
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DANSK DENTAL DEPORT, COPENHAGEN, DENMARK
OY DENTAL DEPOT, HELSINKI, FINLAND
RITTER A.G., KARLSRUHE, GERMANY
KAVO, GENOVA, ITALY
G.J. AND D. THOLEN, UTRECHT, NETHERLANDS
SANITAS, LISBON, PORTUGAL
SUDENTA, BARCELONA, SPAIN
AKTIEBOLAGET FOSSBERG, STOCKHOLM, SWEDEN
A. KOELLIKER AND CO., ZURICH, SWITZERLAND
L. PORRO LTD., LONDON, ENGLAND
SYBRON AUSTRALIA, NORTH RYDE, AUSTRALIA
FRANKENS DENTAL AND MED., HONG KONG
CENCO CONTINENTAL, DJAKARTA, INDONESIA
COMM. HOUSE, KHODJASTEH, TEHERAN, IRAN
DENIALON CO., INC., TEL-AVIV, ISRAEL
HAKASUI TRADING COMPANY, LTD., OSAKA, JAPAN
DR. SHIM-HYUN, DR. YOUN, SEOUL, KOREA
ETS. SABAS J. MOHBAT, BEYROUTH, LEBANON
EASTERN DENTAL SUPPLY, 375 N BRIDGE ROAD, SINGAPORE
N.K. DENTAL SUPPLY, PENANG, MALAYSIA
EARLY BROS., CHRIST CHURCH, NEW ZEALAND
CONSOLIDATED DENTAL, JOHANNESBURG, SOUTH AFRICA
HEINRCHS TECHNICAL OFF., CAIRO, EGYPT
CHUANING COMPANY, TAIPEI, TAIWAN
SAMOS, TUNIS, TUNISIA
MICRONESIAN SALES CO., AGANA, GUAM
CHIMILABO, CASABLANCA, MOROCCO
KISSINGER

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, DENTISTS, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 10-Jan-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
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Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770009-1044
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t19770165/aaaacfen.tel
Line Count: 209
Litigation Code IDs:
Litigation Codes:
Litigation History:
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Message ID: 1de9b6db-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
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Previous Classification: n/a
Previous Handling Restrictions: n/a
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Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 15-Oct-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 3630490
Secure: OPEN
Status: NATIVE
Subject: DENTAL OPERATING LIGHT, MECHANICAL HAZARD, (RECALL NO. T-024-7).
TAGS: OGEN, ETRD, TBIO, XX
To: MEXICO LA PAZ MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/1de9b6db-c288-dd11-92da-001cc4696bcc
Review Markings:
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Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
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